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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,152	03/20/2002	Heinrich Leonhardt	101195-70	6299
27387	7590	09/27/2004	EXAMINER	
NORRIS, MC LAUGHLIN & MARCUS, P.A. 875 THIRD AVE 18TH FLOOR NEW YORK, NY 10022			NICHOLS, CHRISTOPHER J	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/031,152	LEONHARDT ET AL.
	Examiner	Art Unit
	Christopher J Nichols, Ph.D.	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 August 2004.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 10-17 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 10,11,14,15, 16 and 17 is/are rejected.
 7) Claim(s) 12 and 13 is/are objected to.
 8) Claim(s) 10-17 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3.20.02</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 August 2004 has been entered.
2. The inclusion of Derer *et al.* (January 2002) "A novel approach to induce cell cycle reentry in terminally differentiated muscle cells." The FASEB Journal **16**(1): 132-133 has been taken into consideration by the Examiner.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

4. The Objection to claims **9-11** as set forth at pp. 2 ¶4 of the previous Office Action (3 March 2004) is *withdrawn* in view of Applicant's amendments (30 August 2004).
5. The Rejection of claims **10-13** under 35 U.S.C. §112 ¶1 as set forth at pp. 2-7 ¶5-16 of the previous Office Action (3 March 2004) is *withdrawn* in view of Applicant's amendments (30 August 2004).
6. The Rejection of claim **10** under 35 U.S.C. §112 ¶1 as set forth at pp. 7-9 ¶17-22 of the previous Office Action (3 March 2004) is *withdrawn* in view of Applicant's amendments (30 August 2004).
7. The Rejection of claim **10** under 35 U.S.C. §102(b) as set forth at pp. 9 ¶23 of the previous Office Action (3 March 2004) is *withdrawn* in view of Applicant's amendments (30 August 2004).

Maintained Objections And/Or Rejections

Claim Objections

8. Claims **12** and **13** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

35 U.S.C. § 282 Presumption of validity

"A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the

validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim."

MPEP §1701
"Office Personnel Not To Express Opinion on
Validity or Patentability of Patent"

Every patent is presumed to be valid. 35 U.S.C. 282, first sentence. Public policy demands that every employee of the United States Patent and Trademark Office (USPTO) refuse to express to any person any opinion as to the validity or invalidity of, or the patentability or unpatentability of any claim in any U.S. patent, except to the extent necessary to carry out

- (A) an examination of a reissue application of the patent,
- (B) a reexamination proceeding to reexamine the patent, or
- (C) an interference involving the patent.

The question of validity or invalidity is otherwise exclusively a matter to be determined by a court. Members of the patent examining corps are cautioned to be especially wary of any inquiry from any person outside the USPTO, including an employee of another U.S. Government agency, the answer to which might indicate that a particular patent should not have issued. No USPTO employee may pursue a bounty offered by a private sector source for identifying prior art. The acceptance of payments from outside sources for prior art search activities may subject the employee to administrative disciplinary action.

When a field of search for an invention is requested, examiners should routinely inquire whether the invention has been patented in the United States. If the invention has been patented, no field of search should be suggested.

Employees of the USPTO, particularly patent examiners who examined an application which matured into a patent or a reissued patent or who conducted a reexamination proceeding, should not discuss or answer inquiries from any person outside the USPTO as to whether or not a certain reference or other particular evidence was considered during the examination or proceeding and whether or not a claim would have been allowed over that reference or other evidence had it been considered during the examination or proceeding. Likewise, employees are cautioned against answering any inquiry concerning any entry in the patent or reexamination file, including the extent of the field of search and any entry relating thereto. The record of the file of a patent or reexamination proceeding must speak for itself.

Practitioners can be of material assistance in this regard by refraining from making improper inquiries of members of the patent examining corps. Inquiries from members of the public relating to the matters discussed above must of necessity be refused and such refusal should not be considered discourteous or an expression of opinion as to validity or patentability.

9. Claims 10, 11, 14, 15, 16, and 17 are rejected under 35 U.S.C. §102(e) as being anticipated by US 6,358,739 (19 March 2002) Baetge *et al.* US 6,358,739 for the reasons as set forth at pp. 10 ¶24 in the previous Office Action (3 March 2004).

10. Applicant traversed the rejection of the claims on the following grounds: (a) issue US patents are not presumed to be enabled and (b) US 6,358,739 lacks written description of the claimed invention

11. Applicant's arguments have been taken into consideration and are not found persuasive for the following reasons.

12. On "(a)", it is clearly stated in the MPEP §1701 that USPTO Employees lack the authority to deny priority as the claimed subject matter of issued US Patents are presumed valid and in compliance with all statutes per 35 U.S.C. §282. Since priority is a direct function of 35 U.S.C. §119(e), if granted by the Examiner, it is taken to be valid. MPEP §1701 strictly prohibits USPTO personal from questioning the validity of an issued US patent. Thus the Examiner lacks the authority to grant the attorney's request.

13. Furthermore, the authority to question compliance with any or all of these statutes rests solely with the Examiner at the time of filing to prove a *prima facia* case establishing that the application in question fails to meet requirement(s) (see MPEP §700 & §2100). Once the application issues or "patents" it is presumed valid and enabled. Prosecution has been closed and can only be reopened by re-examination, re-issue, and/or court challenge (MPEP §1400, §1200, and §2200; 35 U.S.C. §251).

14. If a member of the public does not agree that the patent is valid with any or all of the statutes, the question must be address by a court challenge [see *New Railhead Mfg., L.L.C. v.*

Vermeer Mfg. Col., 298 F.3d 1290, 1294, 63 USPQ2e 1843, 1846 (Fed. Cir. 2002)]. Thus the Examiner is the wrong venue to grant the attorney's request.

15. On "(b)", US 6,358,739 teaches a fusion protein comprising VP22 fused to SV40 large T antigen or SV40 small T antigen thus meeting the limitations of claims 10 and 11 (claims 1 and 2). The recitation in the claims "a protein for inducing the proliferation of terminally differentiated cells" and "inducing terminally differentiated cells to divide" are met by US 6,358,739 because instant claim 11 lists SV40 T antigen as a member of this genus.

16. Also, US 6,358,739 teaches a fusion protein comprising a poly-HIS tag thus meeting the limitations of claims 16 (Col. 11 lines 48-55).

17. Concerning the description of how the VP22-SV40 fusion protein was manufactured in claim 17, US 6,358,739 teaches production of the claims VP22-SV40 fusion protein via expression in host cells (Example 1). Furthermore, it has been established by the courts that a product inherently possesses characteristics of that product (i.e. including the amino acid sequence of a protein). See, e.g., *Ex parte Gray*, 10 USPQ 2d; *In re Best*, 195 USPQ 430). In addition,

"the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Accordingly, since the issue in the present appeal is whether the prior art factor is identified or patently indistinct from that of the material on appeal, appellants have the burden of showing that inherency is not involved". *Ex parte Gray*, 10 USPQ 2d 1922 (1989); *In re Best*, 195 USPQ 430 (CCPA 1976).

18. Moreover, when the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983). Lastly it is noted that the courts have held that when

the prior art product reasonable appears to be the same as that claimed, but differs by process in which it is produced, a rejection of this nature is eminently fair and the burden is upon the appellants to prove, by comparative evidence, a patentable difference (*In re Brown*, 173 USPQ 685).

19. Claims 10, 11, 14, 15, and 17 are rejected under 35 U.S.C. §102(e) as being anticipated by US 6,451,601 (17 September 2002) Baetge *et al.* US 6,451,601 for the reasons as set forth at pp. 10 ¶25 in the previous Office Action (3 March 2004).

20. Applicant traversed the rejection of the claims on the following grounds: **(a)** issue US patents are not presumed to be enabled and **(b)** US 6,451,601 lacks written description of the claimed invention

21. Applicant's arguments have been taken into consideration and are not found persuasive for the following reasons.

22. On “**(a)**”, it is clearly stated in the MPEP §1701 that USPTO Employees lack the authority to deny priority as the claimed subject matter of issued US Patents are presumed valid and in compliance with all statutes per 35 U.S.C. §282. Since priority is a direct function of 35 U.S.C. §119(e), if granted by the Examiner, it is taken to be valid. MPEP §1701 strictly prohibits USPTO personal from questioning the validity of an issued US patent. Thus the Examiner lacks the authority to grant the attorney's request.

23. Furthermore, the authority to question compliance with any or all of these statutes rests solely with the Examiner at the time of filing to prove a *prima facia* case establishing that the application in question fails to meet requirement(s) (see MPEP §700 & §2100). Once the

application issues or “patents” it is presumed valid and enabled. Prosecution has been closed and can only be reopened by re-examination, re-issue, and/or court challenge (MPEP §1400, §1200, and §2200; 35 U.S.C. §251).

24. If a member of the public does not agree that the patent is valid with any or all of the statutes, the question must be addressed by a court challenge [see *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Col.*, 298 F.3d 1290, 1294, 63 USPQ2e 1843, 1846 (Fed. Cir. 2002)]. Thus the Examiner is the wrong venue to grant the attorney’s request.

25. On “(b)”, US 6,451,601 teaches a fusion protein comprising VP22 fused to SV40 large T antigen or SV40 small T antigen thus meeting the limitations of claims 10 and 11 (claims 1 and 2). The recitation in the claims “a protein for inducing the proliferation of terminally differentiated cells” and “inducing terminally differentiated cells to divide” are met by US 6,451,601 because instant claim 11 lists SV40 T antigen as a member of this genus.

26. Also, US 6,451,601 teaches a fusion protein comprising a poly-HIS tag thus meeting the limitations of claims 16 (Col. 12 lines 55-62).

27. Concerning the description of how the VP22-SV40 fusion protein was manufactured in claim 17, US 6,451,601 teaches production of the claims VP22-SV40 fusion protein via expression in host cells (Example 1). It has been established by the courts that a product inherently possesses characteristics of that product (i.e. including the amino acid sequence of a protein). See, e.g., *Ex parte Gray*, 10 USPQ 2d; *In re Best*, 195 USPQ 430). In addition,

“the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Accordingly, since the issue in the present appeal is whether the prior art factor is identified or patently indistinct from that of the material on appeal, appellants have the burden of showing that inherency is not involved”. *Ex parte Gray*, 10 USPQ 2d 1922 (1989); *In re Best*, 195 USPQ 430 (CCPA 1976).

Art Unit: 1647

28. Moreover, when the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983). Lastly it is noted that the courts have held that when the prior art product reasonable appears to be the same as that claimed, but differs by process in which it is produced, a rejection of this nature is eminently fair and the burden is upon the appellants to prove, by comparative evidence, a patentable difference (*In re Brown*, 173 USPQ 685).

Summary

29. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN
September 22, 2004

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER